C 21

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for a measured resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath.

REMARKS

Status of the Claims

Claims 11-38 are pending in this application. Claims 13, 15, 18, 20, 21, 23, 24, 25, 29, 31, 32, 33, and 38 are amended to correct typographical and form errors. As such, Applicants respectfully submit that no new matter is introduced by the present amendment. Upon entry of the present amendment, claims 11-38 are pending and presented for consideration. A marked-up copy of amended claims and a clean copy of all pending claims as amended herein are attached.

Objections to the Drawings

The drawings were objected to as failing to comply with 37 C.F.R. 1.84 (p)(5) because according to the Office Action, the reference characters 22 and 24 in the description for FIG. 5 were not included in the drawing sheet corresponding to FIG. 5, reference character 77 was not included in FIG. 7, reference character 110 was not included in the drawing sheets, and the display controller mentioned in the description for FIG. 12 was not included in the drawing sheet corresponding to FIG. 12. Applicants amend herein the specification to remove reference number 24 from the description of FIG. 5 because the display 24 is not shown in FIG. 5. Applicants submit corrections to FIGS. 5 and 7 to address Examiner's rejections to the drawings regarding processor 22 and right sight 77.

Applicants respectfully submit that current position 110 appears in originally filed FIG. 9 on the left-hand side of the drawing. Applicants enclose a marked-up copy of FIG. 9 that highlights the location of reference character 110 for the Examiner's convenience.

Also, Applicants request a clarification of the objection based on "display controller (FIG. 12)" that appears on page 2 of the Office Action. Applicants respectfully submit that no where in Applicants' specification does "display controller (FIG. 12)" appear. Applicants also submit that FIG. 12 is a flowchart of an algorithm executed by the exhalation assist device embodied in FIG. 1. Applicants further submit that display controller 12 is shown in originally filed FIG. 1. Applicants have attached to this response a marked-up copy of FIG. 1 that highlights the location of display controller 12.

Applicants also submit an additional correction to FIG. 7 and a correction to FIG. 14 for the Examiner's approval. Applicants have amended FIG. 7 to change reference character from 82' to 82 to conform to the description of FIG. 7. (See page 15 of the specification.) Applicants have also amended FIG. 14 to include reference number 210, which was mentioned in the specification on page 31, line 23, but not included in the originally filed drawings. Applicants attach marked-up copies of FIGS. 5, 7, and 14 and submit amended formal drawings for the Examiner's approval. Applicants believe that the amendments to the drawings introduce no new matter.

Objections to the Specification

The Examiner objected to the specification because of informalities on pages 6, 10, 13, 15, and 18. Applicants herein amend the specification to correct a number of typographical errors as well as to remove "display 24" from the description of FIG. 5 on page 11, line 6. Applicants submit that no new matter is added. Applicants believe that the amendments to the specification together with the amendment to FIG. 7 to change reference character 82' to 82 should overcome the Examiner's objections.

Rejections Under 35 U.S.C. §112

Claims 11-26, 29, 31-33, and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Applicants respectfully point out that there is sufficient antecedent basis for "...said ventilator pneumatic system..." that occurs in line 4 of claim 11. Applicants submit that line 1 of claim 11 states "[a] ventilator control system for controlling a ventilator pneumatic system...." Applicants

also believe that there is sufficient antecedent basis in claim 16 for "said ventilator pneumatic system." Applicants direct the Examiner to line 1 of claim 16, which states "[a] method for controlling a ventilator pneumatic system ...." Accordingly, Applicants believe that there is sufficient antecedent basis for "...said ventilator pneumatic system..." in line 4 of claim 16.

In addition, Applicants believe that there is sufficient antecedent basis for "...the ventilator pneumatic system..." in claim 19, line 2. Claim 19 depends from claim 16. As discussed above, claim 16 provides sufficient antecedent basis for "ventilator pneumatic system" (see line 1 of claim 16). Since claim 19 depends from claim 16, Applicants believe that there is sufficient antecedent basis for "the ventilator pneumatic system" in claim 19 as well.

Also, the Office Action states that there is insufficient antecedent basis for "...the patient's pulmonary system..." in line 10 and 13 of claim 21. Applicants respectfully direct the Examiner to line 6 of claim 21 that states "...a patient's pulmonary system...." As such, Applicants believe that there is sufficient antecedent basis for "the patient's pulmonary system" in claim 21.

Applicants have amended claims 13, 15, 18, 20, 21, 23, 24, 25, 29, 31, 32, 33, and 38 to address Examiner's concerns regarding remaining §112 rejections. Applicants believe that these amendments should satisfy Examiner's concerns in this regard.

Non-Statutory Double Patenting

Claims 11-38 are rejected under the judicially-created doctrine of double-patenting over claims 1-19, 21, 28, 31, 35, and 39 of U.S. Patent No. 5,931,160.

Applicants respectfully request that these rejections be held in abeyance until a determination of allowable subject matter is made.

Rejection of Claims under 35 U.S.C. §102(e)

Claims 11, 16, and 31 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,000,396 to Melker et al. (hereinafter "Melker"). Applicants respectfully traverse the above rejection.

Applicants' claim 11 recites a ventilator control system including a controller comprising a breath control structure. The controller receives input values from a user for setting one or more breath parameters within the breath control structure and adjusts a plurality of controls within a ventilator pneumatic system in response to the breath control structure.

Applicants have defined a breath control structure as "a collection of phase control structures ... and phase switching rules." (See page 25, lines 16-18 in Applicants' specification.) Applicants define a phase control structure as "a collection of ventilator control settings and an array of waveform samples." (See page 25, lines 18-20.) Each breath taken by a patient includes several phases. Applicants' ventilator control system operates by utilizing the controller's breath control structure to determine how and when to switch the ventilator to a new phase of a breath for a patient within a single breath. (See page 26, lines 19-29.)

Applicants believe that Melker discloses a ventilator control system that adjusts the ventilation flow rate within a specified ventilation mode. Instead of teaching Applicants' claimed controller comprising a breath control structure, Melker merely teaches a microprocessor that adjusts ventilation controls according to settings only within a particular mode of ventilation. (See column 15 of Melker.) Moreover, Melker fails to teach or suggest a controller that includes a breath control structure or a controller that adjusts the plurality of ventilator controls in response to the breath control structure. In fact, Applicants believe that Melker's control system operates to adjust ventilation flow rates within a set of ventilation modes, see column 2, lines 45-50, rather than in response to the breath control structure, a collection of phase control structures and phase switching rules that determine how and when to switch to a new phase of a breath within a single breath, as claimed by Applicants. Thus, Melker neither teaches nor suggests a controller that includes a breath control structure. Melker also fails to teach a controller that adjusts the plurality of ventilator controls in response to the breath control structure. Thus, Melker does not teach each and every element of Applicants' claimed invention at least because Melker does not teach a control system that includes a breath control structure. Accordingly, Melker is an improper reference under 35 U.S.C. §102.

Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under §102.

Applicants' claims 16 and 31 also include a breath control system as a claimed element. For example, Applicants' claim 16 teaches a method for controlling a ventilator pneumatic system. A step within claim 16 includes adjusting a plurality of controls within the ventilator pneumatic system in response to the breath control structure. Claim 31 discloses a ventilator control system that includes a database for storing a plurality of patient protocols, each patient protocol including a set of breath control structures. The ventilator control system of claim 31 further includes a controller for adjusting the plurality of controls within the ventilator pneumatic system using the breath control structure of a selected patient protocol. As described above, Melker fails to teach or suggest a controller that includes a breath control structure or that adjusts a plurality of ventilator controls in response to a breath control structure. Accordingly, Melker does not teach each and every element of Applicants' claimed invention as recited in claims 16 and 31. Applicants respectfully request reconsideration and withdrawal of these § 102 rejections.

CONCLUSION

In view of the foregoing amendments and arguments presented herein, Applicants respectfully urge that claims 11-38 are now in condition for allowance. The Examiner is invited to call the undersigned at (617) 248-7044 if the Examiner believes that a telephone conversation could be helpful in expediting prosecution of the application.

Respectfully submitted,

Date: June, 5, 2002

Reg. No. 44,244

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MARKED-UP COPY OF AMENDMENTS TO THE SPECIFICATION

The paragraph beginning on page 6, line 24, and ending on page 7, line 10, is amended herein as follows:

> A sensor monitoring system 19, including an exhalation flowmeter 11 a circuit resistance sensor 9 and a pressure sensor 7 in communication with the flexible airway tubing 21, provide signals to a embedded controller 14 relating to airway pressure, flow and resistance. These measured values are stored in a database 13. These values are also compared with values preselected by a user by way of the embedded controller 14 to calculate the amount of negative pressure to be generated in the ventilator 17 in order to produce an airway pressure greater than zero and less than positive end-expiratory pressure. A pneumatic system 41 regulates the flow of gas delivered from the source of pressurized gas 45 through a Venturi valve within the ventilator 17 to produce this negative pressure. One embodiment of such a pneumatic system 41 is described in U.S. patent number 5,664,563, owned by the assignee of the present invention, incorporated herein by reference. A pressure sensor 51 measures the amount of negative pressure produced within the ventilator 17 and transmits these data to the embedded controller 14. These data are stored in the database 13 and displayed on the display 24 of the display controller 12.

The paragraph beginning on page 7, line 11, and ending on line 22, is amended herein as follows:

> Initially, the clinician 16 enters target values into the system 10 by way of the input device 26 of the display controller 12. Each of these target values is compared with a corresponding current value of ventilatory unit pressure, airway pressure, airway flow and airway

resistance by the embedded controller 14. Upon determining that there is a difference between current pressure, flow and resistance values and those values entered by the clinician 16, the embedded controller 14 generates a signal to the pneumatic system 41 so that the pneumatic system 41 changes the amount of negative pressure produced by the ventilator 17. The ventilator 17 is in pneumatic communication with a flexible airway tubing 21 capable of attachment to a patient 20. The clinician 16 can also directly adjust the pneumatic system 41 by manipulating a plurality of controls on the input device 26 of the display controller 12.

The paragraph beginning on page 7, line 23, and ending on line 29 is amended herein as follows:

The clinician 16 enters numerical data at the display controller 12 relating to the desired level of airway resistance in the flexible airway tubing 21 or relating to the desired amount of negative pressure in the pneumatic system 41. These entered values signal the pneumatic system 41 to change the amount of negative pressure on a per breath basis within the pneumatic system 41 until the pressure in the pneumatic system 41 or the resistance in the flexible airway tubing 21 equals the value entered by the clinician 16.

The paragraph beginning on page 10, line 20, and ending on page 11, line 2, is amended herein as follows:

In more detail, and referring also to FIG. 4, a block diagram of the ventilator 17 in communication with the flexible airway tubing 21 that is the conduit for inhalation from the patient 20 is depicted. The pneumatic system 41 regulates the amount of negative pressure produced within a

rigid chamber 43 by adjusting the flow of gas from a source of pressurized gas 45 through a Venturi valve 47. Within the rigid chamber 43 is a flexible canister 49. Negative pressure produced within the rigid chamber 43 is transmitted to the flexible canister 49 and thus to the patient flexible airway tubing 21 which is in pneumatic communication with the flexible canister 49. In this way, negative pressure is applied to the patient flexible airway tubing 21 to assist the patient's exhalation through the canister 49 into the medical ventilator 17. Pressure within the flexible canister 49 is measured by a pressure sensor 51. These data are transmitted to the embedded controller 14.

The paragraph beginning on page 11, line 3, and ending on line 25 is amended herein as follows:

Now referring also to FIG. 5 a detailed functional block diagram of the ventilator control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider 34 to change or set one or more breath parameters. A change alert panel 36 [on the display 24]informs the clinician 16 of the process, from input to implementation, to assure him that his input information is being processed properly. As noted previously, a change to one or more breath parameters will lead to changes in one or more data structures of the therapy control structure hierarchy. It is noted that FIG. 5 provides an example of a breath parameter change which results in a change at the level of the breath control structure. The validation process includes the processor 22 validating 38 the clinician's inputs and creating 40 a breath control structure which is stored in memory. The display controller 12 transmits the breath control structure to the embedded controller 14 and informs the clinician 16 of successful transmission via the change alert panel 36. The embedded controller 14 initially stores 44 the breath control structure in local memory. The

embedded controller 14 re-validates 46 the settings within the breath control structure. The embedded controller 14 implements 48 the validated breath control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic system 41 for simultaneously changing one or more control settings at the appropriate time. This process enables the user to change or implement a new therapy so that the therapy delivered to the patient is essentially uninterrupted, and the new therapy is synchronized with the next inspiration. If, however, any step in the process is not completed, the clinician is alerted via the panel 36 to the cause of the error and the process is terminated.

The paragraph beginning on page 11, line 26, and ending on page 12, line 8 is amended herein as follows:

The ventilator control system 10 provides two independent feedback paths to assure the clinician 16 that his setting change has been properly implemented. First, the embedded controller 14 calculates a series of breath monitoring values and sends them to the display controller 12, where the values are displayed 60 contiguous to the desired setting controls. The breath monitoring values can be, for example, set breath rate, measured breath rate, set tidal volume, measured inhaled volume, and measured exhaled volume. The display controller 12 also displays 60 a series of measurements (e.g., peak airway pressure, peak airway flow, and PEEP) from the waveform data both numerically and graphically. Second, the display controller 12 displays 54 the continuous waveforms on the display 24 (shown in FIG. 2). The waveforms are derived 56 from raw data from the sensors 19, returned from the embedded controller 14 and passed directly to the display 24 (shown in FIG. 2).

The paragraph beginning on page 13, line 6, and ending on line 12 is amended herein as follows:

As the patient exhales, the system 10 monitors both the patient airway flow and the patient airway pressure. Referring to FIG. 6, if the gas flow is seen to flow into the patient, and the press[u]ure slope is positive, the flow into the patient is considered to be a result of overshoot and no inhalation is triggered (FIG. 6a). If the pressure decreases and the gas flow is into the patient (Step 300), then the total amount of gas inhaled by the patient is measured, and compared to the tr[r]igger volume (Step 310).

The paragraph beginning on page 13, line 13, and ending on line 17 is amended herein as follows:

If the total amount of gas inhaled is greater than the trigger volume and this value has been reached in less than 200 msec, a breath is initiated. If the trigger volume has not been reached and it is taking more than 200 msec, the volume of inhaled gas is continued to be measured until the trigger volume has been reached (Steps 320, 330).

The paragraph beginning on page 18, line 1, and ending on line 13 is herein amended as follows:

By selecting one of the control buttons on the touch display, the clinician 16 can display the control slider 104[6] for the control setting in a fixed location at the right of the screen, as shown in FIG. 9. A scroll bar title 106[8], located near the top of the slider 104[6], indicates the name of the control setting. The full vertical range 108 indicates the allowed set limits. The center slider indicates the current position 110 and the range 112 of the control setting. The upper and lower sliders (114, 116) indicate

the current alarm limit settings. The position 110 of the current setting within the allowable range 112 and within the alarm limits (114, 116) is readily apparent to the clinician. The clinician can move any of the sliders to change the set values in steps of approximately 1% of the allowable range, or with the "Exact" button selected, approximately ten times more precision (i.e., about 0.1% of the allowable range). When the desired value is reached, the clinician depresses the Accept Changes button to change the parameter.

The paragraph beginning on page 21, line 1, and ending on line 17 is amended herein as follows:

Referring again to FIG. 9, the display controller includes software for manipulating the characteristics of the breath parameter Airway Pressure 106 displayed in the control slider 104 on the touch-sensitive display 24. When the clinician 16 selects a control button to display the control slider 10<u>4</u>[6] for Airway Pressure, the display controller 12 dynamically defines a touch zone on the touch-sensitive display. More specifically, touch zones are defined for each slider (i.e., high alarm, low alarm, position and allowable range) within the control slider. Each touch zone is slightly larger than the displayed slider. By way of example only, the touch zone for high alarm may extend into regions 118 to either side of the color coded high alarm region 114. The display controller 12 receives a touch signal when the clinician 16 touches any location within the touch zone and changes the range of the high alarm slider breath parameter in response to the touch signal. In other words, the display controller 12 increases the high alarm limit in response to the clinician 16 touching a location within the region 118 and dragging his finger in a upward path. Because his finger does not obscure the high alarm limit, the clinician can actually see the limit being change as it happens.

The paragraph beginning on page 31, line 1, and ending on line 11 is amended herein as follows:

> The database 13 is electrically coupled to the display controller processor 22 and stores a plurality of patient protocols. Each patient protocol includes at least a set of breath parameters and patient data. The breath parameter may be organized as one or more therapy control structures. The clinician 16 selects a patient protocol by depressing a touch zone on the display 24. The processor 22 copies the selected patient protocol into memory. In the operational mode, the processor 22 instructs the embedded controller 14 to simultaneously adjust the controls of the pneumatic system 18 using the selected patient protocol. In the simulation mode, the simulator 212 simulates the adjustment to the ventilator pneumatic system 41 and the resulting response of the patient's pulmonary system.

MARKED-UP COPY OF AMENDMENTS TO THE CLAIMS

Claims 13, 15, 18, 20, 21, 23, 24, 25, 29, 31, 32, 33, and 38 were amended as follows:

13. (Amended) The ventilator control system of claim 11 further comprising a display in communication with said controller for displaying a user interface comprising software-generated images representing status of [the]a patient's pulmonary system and [the]a set of breath parameters.

15. (Amended) The ventilator control system of claim 11 further comprising a simulator electrically coupled to the controller for simulating [the]a status of a patient's pulmonary system in real time.

18. (Amended) The method of claim 16 further comprising creating a breath control structure from [the]a set of breath parameters.

20. (Amended) The method of claim 16 further comprising displaying software-generated images representing status of [the]a patient's pulmonary system and [the]a set of breath parameters on a display.

21. (Amended) A ventilator control system for simulating status of a patient connected to a ventilator pneumatic system comprising:

a controller comprising a breath control structure, said controller for receiving input values from a user for setting one or more breath parameters within said breath control structure;

a simulator electrically connected to the controller for predicting [the]a status of a patient's pulmonary system by simulating

(a) an adjustment by the controller of a plurality of controls within the ventilator pneumatic system in response to said breath control structure,

(b) a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and

a display in electrical communication with said simulator for providing software-generated images representing predicted status of the patient's pulmonary system and the set of breath parameters.

23. (Amended) The ventilator control system of claim 21 wherein the [user interface]display comprises a touch-sensitive screen.

24. (Amended) A method for simulating a status of [the]a patient's pulmonary system[of a patient], the patient being connected to a ventilator pneumatic system, the method comprising:

creating a breath control structure comprising one or more breath parameters;

predicting the status of the patient's pulmonary system by

(a) simulating an adjustment to a plurality of controls within the ventilator pneumatic system in response to the breath control structure, and

(b) simulating a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and

displaying software-generated images representing [the]a predicted status of the patient's pulmonary system and the breath control structure.

25. (Amended) The method of claim 24 further comprises using the controller to create at least one breath control structure from [the]a set of breath parameters.

29. (Amended) The method of claim 28 wherein a therapy parameter comprises at least one of a time measurement and a characteristic of [the]a patient's pulmonary system.

31. (Amended) A ventilator control system for controlling a ventilator pneumatic system comprising:

a database for storing a plurality of patient protocols, each patient protocol comprising a set of breath control structures; and

a controller for adjusting a plurality of controls within the ventilator pneumatic system using the breath control structure of [the]a selected patient protocol.

32. (Amended) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:

providing a resistance parameter;

measuring [the]gas flow resistance into and out of the lungs of a patient during an inspiration phase, an exhalation phase and a post-breath phase of a breath; and

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured gas flow resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath to control respiration of said patient.

33. (Amended) A method of displaying historical status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:

defining a measurement period;

providing a plurality of breath parameters having user defined target values and actual values, the breath parameters comprising minute volume, inspiration phase, exhalation phase, inspiration/exhalation ratio, breathing rate, spontaneous minute volume, inhale tidal volume, exhale tidal volume, and leakage;

measuring the actual breath parameter values during the measurement period;

generating an integrated graphic for displaying the target values and actual values of the plurality of breath parameters on a display; and

periodically updating [the]input values and measured values included in the graphic display.

38. (Amended) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:

providing a resistance parameter;

setting said resistance parameter equal to a value calculated from monitored gas flow and pressure measurements for the patient, wherein said value is calculated from the following equation;

resistance parameter = (Inspiration Peak Pressure - End Inspiration Plateau Pressure)/ (Inspiration Flow at Peak);

measuring [the]gas flow resistance into and out of the lungs of a patient during an inspiration phase, and exhalation phase, an exhalation phase and a post-breath phase of a breath; and

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for [the]a measured resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath.

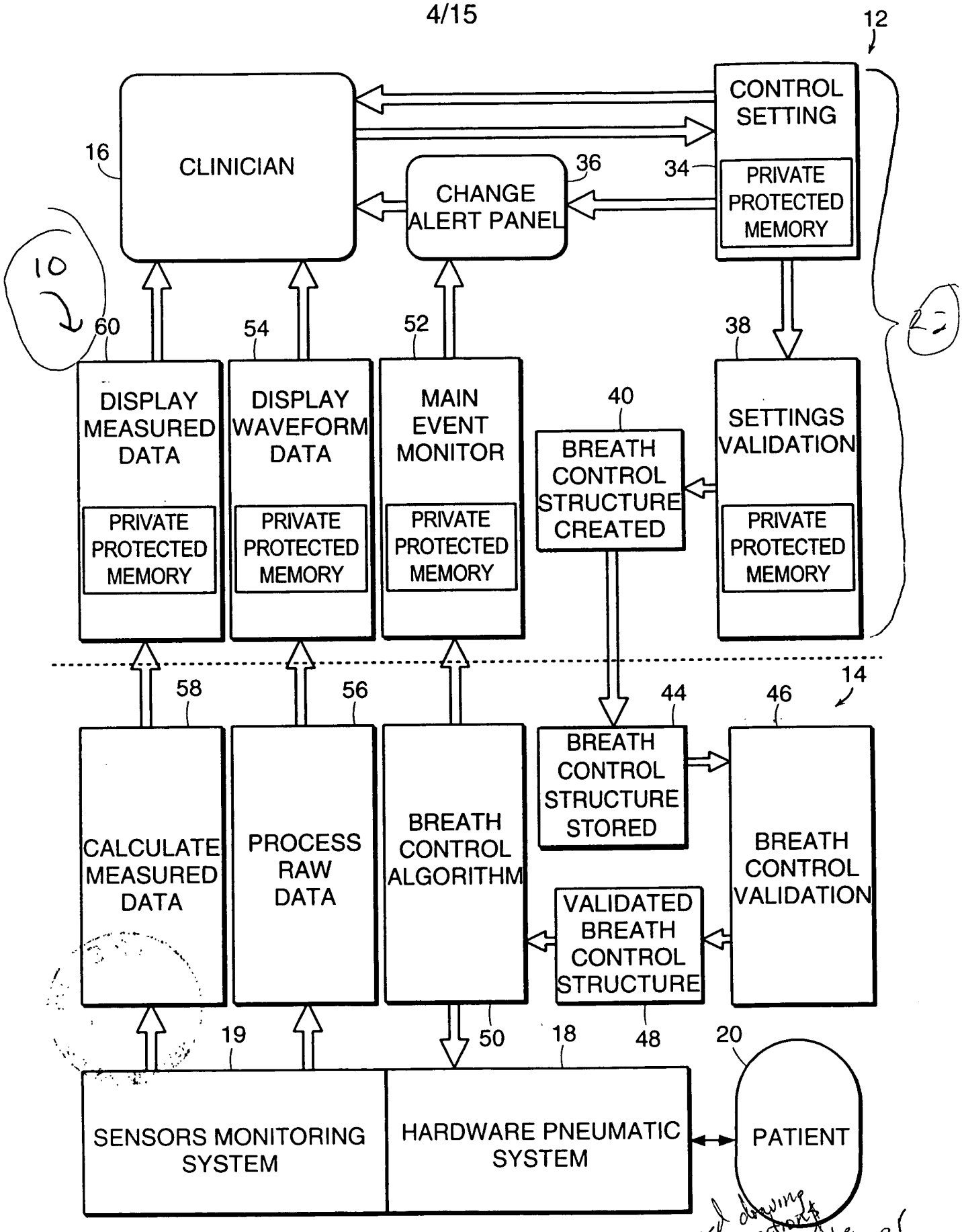


FIG. 5

Proposed drawing corrections approved by the examiner

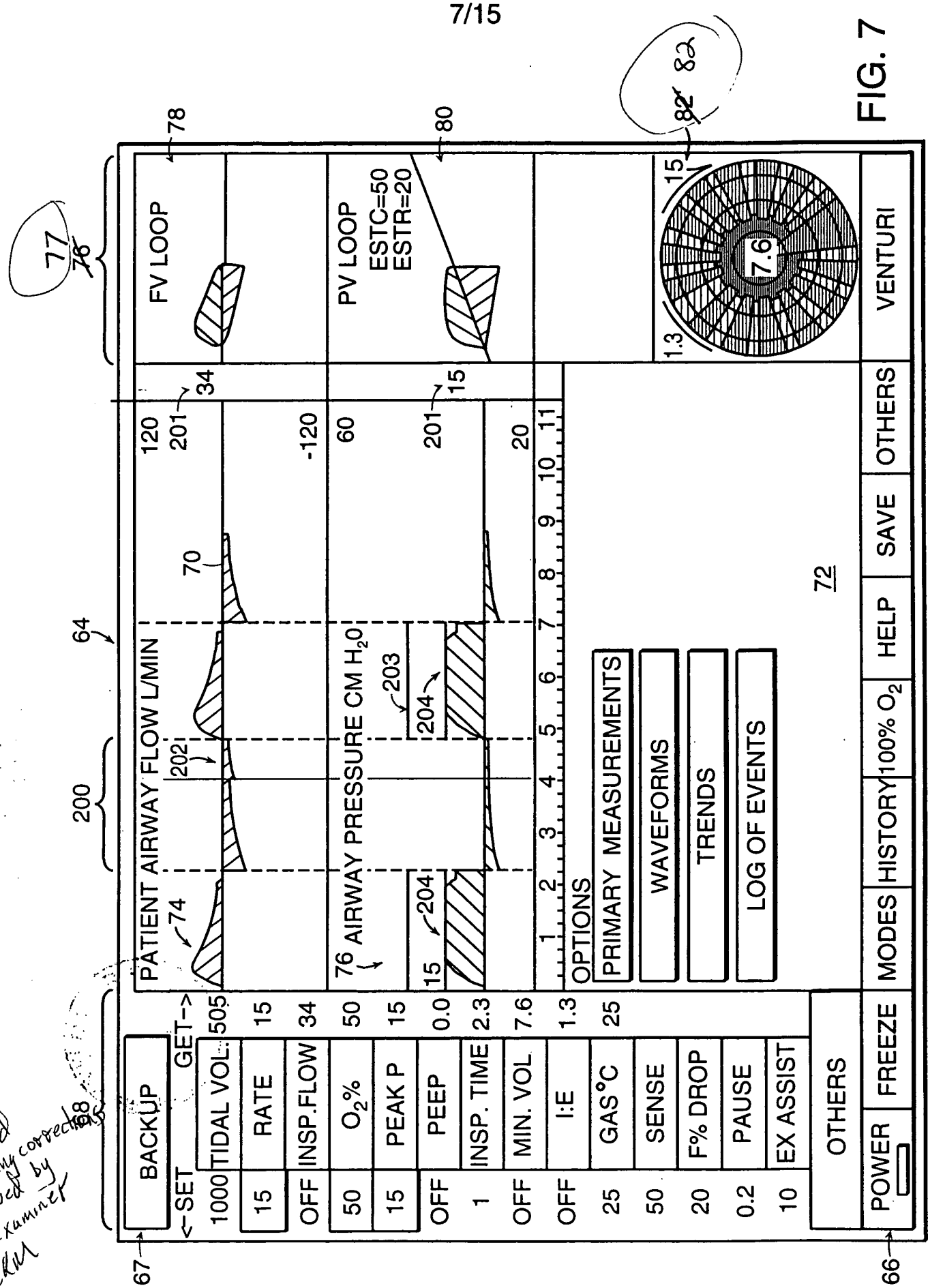
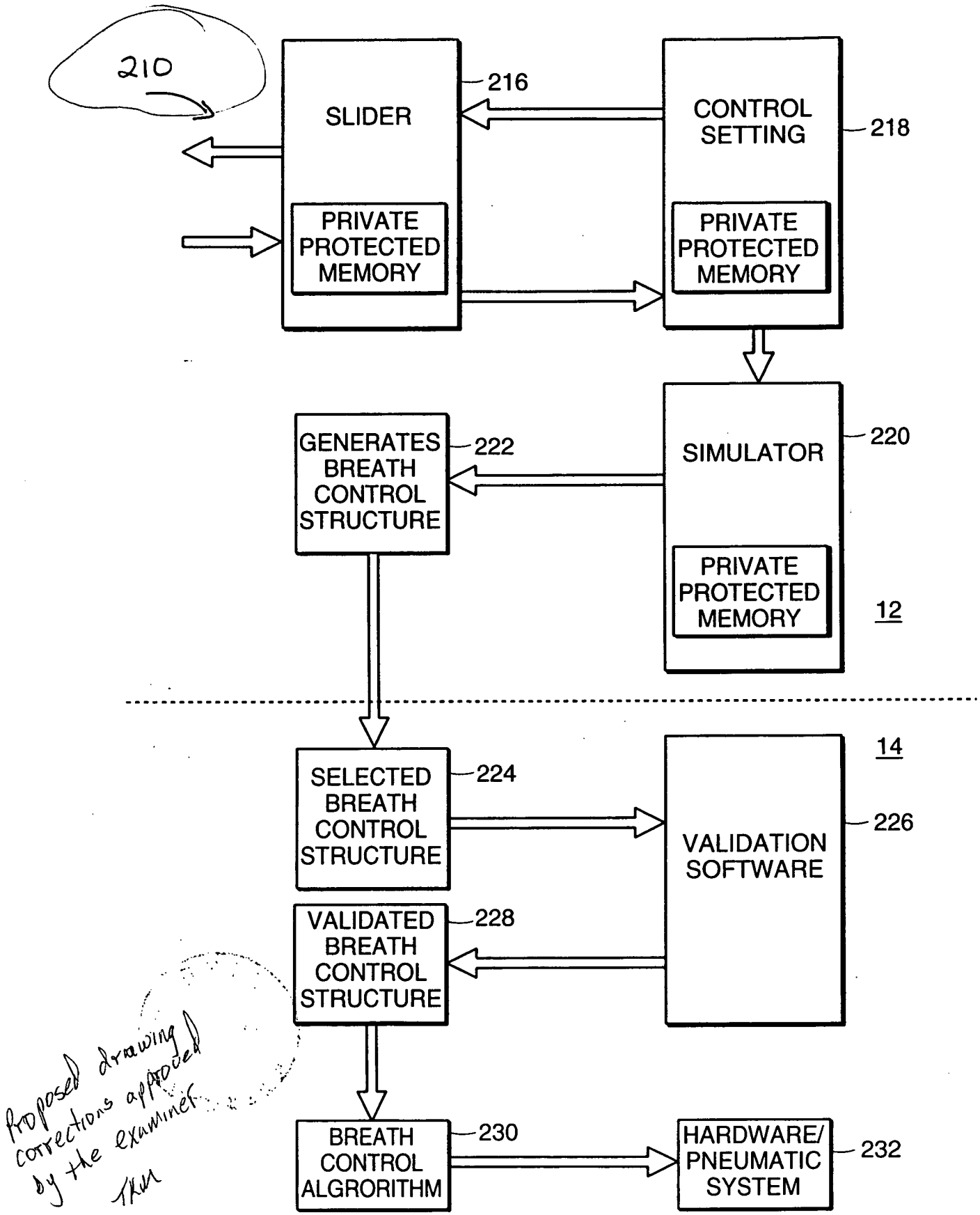


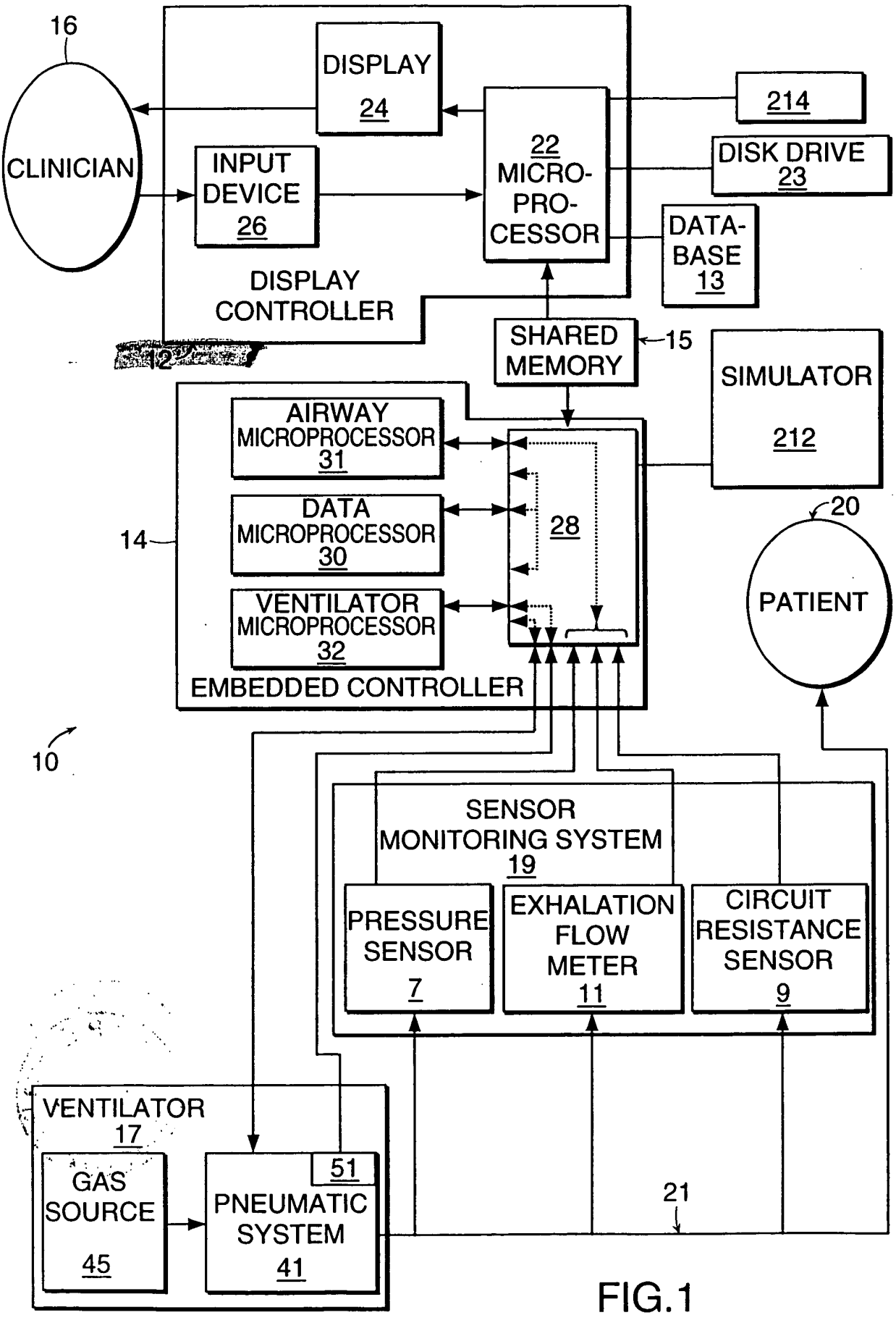
FIG. 7

Proposed drawing corrected approved by the examiner TKM



Proposed drawing corrections approved by the examiner
TKH

FIG. 14


16
CLINICIAN
DISPLAY
24
INPUT
DEVICE
26
22
MICRO-
PRO-
CESSOR
214
DISK DRIVE
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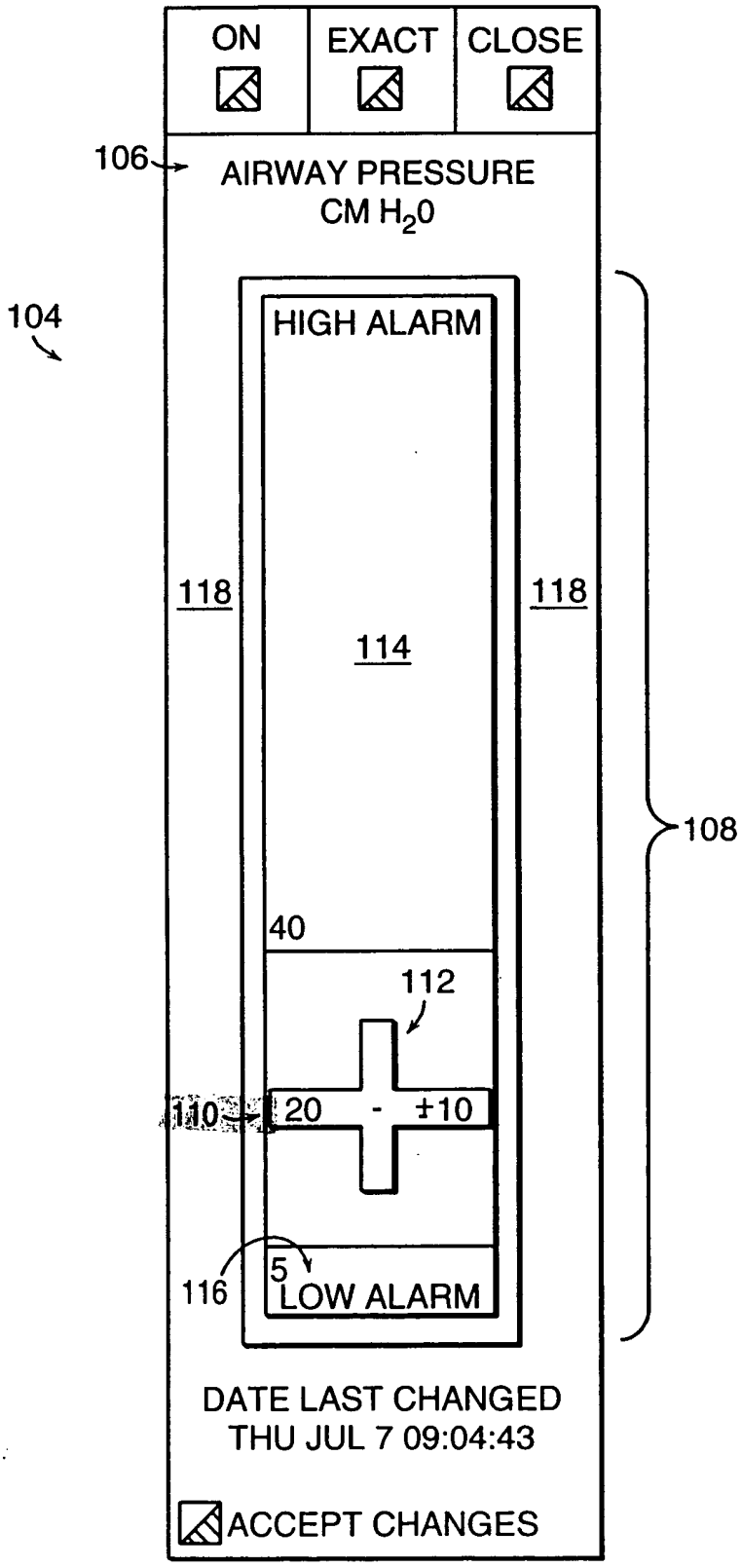
DATA-
BASE
13
DISPLAY
CONTROLLER
SHARED
MEMORY
15
SIMULATOR
212
AIRWAY
MICROPROCESSOR
31
DATA
MICROPROCESSOR
30
VENTILATOR
MICROPROCESSOR
32
28
14
EMBEDDED CONTROLLER
20
PATIENT
10
SENSOR
MONITORING SYSTEM
19
PRESSURE
SENSOR
7
EXHALATION
FLOW
METER
11
CIRCUIT
RESISTANCE
SENSOR
9
VENTILATOR
17
GAS
SOURCE
45
51
PNEUMATIC
SYSTEM
41
21

FIG.1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118
114
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40
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116
5
LOW ALARM
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THU JUL 7 09:04:43
ACCEPT CHANGES

FIG. 9